



# 230.00 -126-881806

Dkt. 43016-A-PCT-US/JPW/AKC/JKM

#11  
D. Williams  
5/5/97

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Philip O. Livingston and Friedhelm Helling  
U.S. Serial No.: 08/196,154 Group Unit: 1806  
Filed : November 16, 1995 Examiner: A. Caputa  
For : GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21

1185 Avenue of the Americas  
New York, New York 10036  
May 2, 1997

Assistant Commissioner for Patents  
Washington, D.C. 20231

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56(c) and §1.97(c), applicants would like to direct the Examiner's attention to the following disclosure which is listed on the attached Form PTO-1449 (Exhibit 1) and attached hereto as Exhibits 2-6:

1. Helling, F., et al. (March 1993) "Increased immunogenicity of GM2 conjugated with KLH and used with adjuvants in patients with melanoma." Proceedings Of The 84th Annual Meeting Of The American 34: 491 (Exhibit 2);
2. Helling, F., et al. (August 1993) "Construction of immunogenic GD-3 conjugate vaccines." Annals Of The New York Academy Of Sciences 690: 396-397 (Exhibit 3);
3. Helling, F., et al. (1994) "GD3 vaccines for melanoma superior immunogenicity of keyhole limpet hemocyanin conjugate." Cancer Research 54: 197-203 (Exhibit 4);
4. Bystryrn, J-C (1990) "Tumor vaccines." Cancer And Metastasis Reviews 9: 81-91 (Exhibit 5); and

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5. Ritter, G., et al. (1990) "Induction of antibodies reactive with GM2 ganglioside after immunization with lipopolysaccharides for *Campylobacter jejuni*." Int. J. Cancer 66: 184-190 (Exhibit 6).

The references, enclosed as Exhibits 2-5, were cited in the Supplementary European Search Report issued in connection with European Application No. 94 90 7279.7, filed August 22, 1995, corresponding to PCT International Application No. PCT/US94/00757, filed January 21, 1994. The subject application is a 371 of PCT/US94/00757. A copy of the Supplementary European Search Report is attached hereto as **Exhibit 7**.

Further, the reference, enclosed as Exhibit 6, was cited by the New Zealand Patent Office during the substantive examination of New Zealand Application No. 261744, filed July 28, 1995, corresponding to PCT International Application No. PCT/US94/00757, filed January 21, 1994. The subject application is a 371 of PCT/US94/00757.

Applicants maintain that the subject invention is novel and nonobvious over the teachings disclosed in the above-identified publications. Accordingly, applicants maintain that the above-identified publications neither disclose nor suggest the invention claimed in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the \$230.00 fee under 37 C.F.R. §1.17(p), is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any other fee is required, authorization is hereby given to charge

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the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

Albert Wai-Kit Chan

I hereby certify that this correspondence  
is being deposited this date with the U.S.  
Postal Service with sufficient postage as  
first class mail in an envelope addressed  
to: Assistant Commissioner for Patents,  
Washington, D.C. 20231.

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## INFORMATION DISCLOSURE CITATION IN AN APPLICATION



08/196.154

Applicant  
Philip O. Livingston and Friedrich Helling

Filing Date  
November 16, 1995

Group Art Unit 1806

U. S. PATENT DOCUMENTS

(use several sheets if necessary)

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**FOREIGN PATENT DOCUMENTS**

DOCUMENT NUMBER

DATE \_\_\_\_\_

COUNTRY

**CLASS**

SUBCLASS

Translation

YES	NO
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**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

Helling, F., et al. "Increased immunogenicity of GM2 conjugated with KLH and used with adjuvants in patients with melanoma." March 1993

Proceedings Of The 84th Annual Meeting Of The American Association For  
Cancer Research 34: 491

Helling, F., et al. "Construction of immunogenic GD-3 conjugate vaccines." August 1993 Annals Of The New York Academy Of Sciences

## EXAMINER

DATE CONSIDERED \_\_\_\_\_

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE



DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
D,P, X	PROCEEDINGS OF THE 84TH ANNUAL MEETING OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH, vol. 34, March 1993, page 491 XP002023381 HELLING ET AL: "INCREASED IMMUNOGENICITY OF GM2 CONJUGATED WITH KLH AND USED WITH ADJUVANTS IN PATIENTS WITH MELANOMA" * abstract 2929 *	1-20	A61K45/05 A61K31/70 A01N43/08 A61K39/00 A61K39/385
P,X	ANNALS OF THE NEW YORK ACADEMY OF SCIENCES,USA, vol. 690, 12 August 1993, pages 396-397, XP000616247 HELLING ET AL: "CONSTRUCTION OF IMMUNOGENIC GD3-CONJUGATE VACCINES" * the whole document *	1-20	
P,X	CANCER RESEARCH, vol. 54, 1 January 1994, pages 197-203, XP002023382 HELLING ET AL: "GD3 VACCINES FOR MELANOMA: SUPERIOR IMMUNOGENICITY OF KEYHOLE LIMPET HEMOCYANIN CONJUGATE VACCINES" * the whole document *	1-20	TECHNICAL FIELDS SEARCHED (Int.Cl.5)  A61K
A	CANCER AND METASTASIS REVIEWS, vol. 9, 1990, pages 81-91, XP000616188 BYSTRYN: "TUMOR VACCINES" * the whole document *		
The supplementary search report has been drawn up for the claims attached hereto.			
Place of search <b>THE HAGUE</b>		Date of completion of the search <b>22 January 1997</b>	Examiner <b>Sitch, W</b>
<b>CATEGORY OF CITED DOCUMENTS</b>  X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document  T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons  & : member of the same patent family, corresponding document			

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Exhibit 7